Kaczmarek, Chris

From: Taub, Cynthia <CTaub@steptoe.com>
Sent: Friday, August 09, 2013 1:21 PM
To: Ross, Philip; Kaczmarek, Chris; Talbert, Stephanie (ENRD) (Stephanie.Talbert@usdoj.gov)
Cc: Goldberg, Seth; Allison_Starmann@americanchemistry.com
Subject: Settlement Confidential - Proposed Meeting Schedule
Attachments: Cover Letter re Settlement Discussions.pdf; Proposed 158W Settlement Meeting Schedule with EPA DOC (2).pdf

All-

Please see the attached regarding a proposed schedule of meetings to discuss the 158W rule.

We look forward to your response,

Cynthia

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PRIVILEGED AND CONFIDENTIAL
SETTLEMENT COMMUNICATIONS

August 9, 2013

Via E-Mail
Stephanie J. Talbert
United States Department of Justice
Environmental Defense Section
P.O. Box 7611
Washington, DC 20044

Philip Ross
Chris Kaczmerek
Office of General Counsel
United States Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: Settlement Discussions in ACC v. EPA, Docket 13-1207 (D.C. Cir)

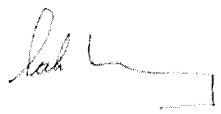
Dear Ms. Talbert, Mr. Ross and Mr. Kaczmerek:

In accordance with our discussion of July 23, 2013, I have attached a proposed schedule of meetings to discuss substantive issues and questions the ACC Biocides Panel has regarding the new 40 CFR Part 158 Subpart W regulation. We envision each of the three meetings we have suggested as including client personnel, so that the Panel member companies can explain the practical issues they see, and EPA personnel with substantive knowledge who can provide informed views. To be productive, we suggest each meeting be scheduled for a day: say 10 – 12:30 and then 2 – 4:30. This will allow time for initial discussion and then some reaction and follow up. In addition, to ensure we make progress, we suggest that each meeting be memorialized with an agreement on concrete action items, assignments and deadlines, with dates to evaluate progress and, as appropriate, to meet again. Finally, as we discussed on July 23, the meetings should be handled as settlement discussions. Discussions will not be used by either side if settlement does not resolve all outstanding issues and litigation resumes.

As the rule is currently in effect and Panel member companies have a lot of questions as to how it will be implemented, we would like to schedule the meetings as promptly as possible. We welcome your input on the proposed meeting contents, format and timing and look forward to working with you toward successfully resolving this matter.

Please feel free to contact me at SGoldberg@steptoe.com or (202) 429-6213 for further discussion. Thank you.

Sincerely,



Seth Goldberg

Attachment

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SETTLEMENT COMMUNICATIONS

August 9, 2013

Appeal of 40 CFR Part 158 Subpart W
Proposed Settlement Meeting Topics and Schedule

First Meeting: Food-Related Issues. Proposed Time Frame: August 19 – 30

1. Timing and content of guidance on what is a food use and availability of Use Site Index, if separate. Will there be an opportunity to comment?
2. What types of products will be subject to either tolerances or "408" reviews? How will those be conducted and how do they differ from what EPA currently does?
3. Differentiation of direct and indirect food uses.
4. Applicability of new requirements to inert ingredients.
5. What are the residue chemistry requirements, what guidance should be used in meeting them and how they will be used in risk assessments?
6. How will the footnote in PRIA 3 waiving fees for newly-required tolerances be implemented?
7. Explanation and, if necessary, correction of 200 ppb threshold value.

Second Meeting: Down the Drain (Ecotox and Environmental Fate), Implementation Issues, and Risk Assessment. Proposed Time Frame: September 9 – 20

1. **Down the Drain Issues**
    a. To what uses will new tests apply? What test material should be used?
    b. What are the triggers for higher tier ecotox and environmental fate requirements?
    c. How is the EEC to be calculated for antimicrobials?
    d. How will EPA use these new data?
    e. How will these data requirements be phased-in?
    f. Timing and content of implementation guidance. Will there be an opportunity to comment?

2. **Implementation Issues**
    a. Timing and content of implementation guidance. Will there be an opportunity to comment?
    b. How will new data requirements be imposed on both new applications and existing registrations? Particularly for new "food" and "surface residue" assessments.
    c. How will EPA handle inert ingredient tolerances and "food clearances" that are not tolerances? Differentiation of data requirements between actives and formulated products.
    d. When/how will EPA provide guidance for performing residue deposition and dissipation work?

3. **Risk Assessment**
    a. How will the data required under the new rule be used in risk assessments? Registrants and applicants should be able to duplicate EPA's analysis to know how their products will be viewed, especially for new "food," ecotox and environmental fate requirements.
    b. What training is being given to staff?
    c. Is there guidance on risk assessment and, if not, when will there be?
    d. How does EPA plan to ensure transparency in risk assessment process?

Third Meeting: Treated Articles, Technical Corrections and Food Follow up. Proposed Time Frame: September 23 – October 4

1. What treated articles or uses will be subject to "food" reviews? How does EPA plan to implement that in labels? How will revised labeling be phased-in?
2. How will 200 ppb threshold be calculated? What will the substance of those reviews look like and how will those reviews differ from non-food treated articles? Under what circumstances will EPA perform or use non-dietary ingestion data?
3. Definition of fungicide as it applies to materials preservatives and other non-public health products.

Fourth and Subsequent Meetings: Topics and dates to be decided as appropriate.